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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,225	04/30/2001	Bernhard Erni	9508-005-999	4478

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PENNIE & EDMONDS LLP
COUNSELLORS AT LAW
1155 Avenue of the Americas
New York, NY 10036-2711

EXAMINER	
BORIN, MICHAEL L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,225	Applicant(s) Erni et al.
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 13, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *09/026,904* .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. The Examiner acknowledges the response to restriction requirement filed 12/13/2002. Applicant's arguments were deemed persuasive, and the restriction requirement is hereby withdrawn. All claims, 1-6, are addressed.

Claim Rejections - 35 U.S.C. § 112, second paragraph.

2. Claims 1,2, and claims depending thereupon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A Claims 1,2 seem to lack internal antecedent basis as they, first, address a "specific small organic compound", and later "a test compound". It is not clear whether these two compounds are the same, and if not, what is the difference between the two. Amendment of the claim to, e.g., " a test small organic molecule compound" is suggested.

B. Claims 1-6: The term "small organic molecule" is vague and indefinite. The term is not defined by the claims. The specification, although providing particular examples, does not provide a standard for ascertaining what constitutes a "small organic molecule", and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

C. Claim 2: It is not clear whether the term "radiolabeled" (line 4 of the claim) refers to N-acetylglucoseamine alone or to both N-acetylglucoseamine and glucose. Further, it is not clear whether the terminal phosphate acceptor isolated and measured in step (b) is radiolabeled (i.e., as was claimed in the claims of the parent application). If "radiolabeled" is meant, and in step (a) radiolabeled refers only to N-acetylglucoseamine, ten it would not be clear how measurements in step (b) are carried out in the case of glucose being a terminal phosphate acceptor.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

4. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of US 6,245,502 for the following reasons: Both claims of the patent and instant application are drawn to a screening assay for inhibitors of enzyme I, wherein the assay steps are essentially the same, except that claims of the patent are directed to the peptides as test compounds, and instant claims address, more broadly, any "small organic molecules" as test compounds. As peptides are "small organic molecules" too, the scopes of the claims overlap.

Claim Rejections - 35 USC § 103.

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-6 are rejected under 35 U.S.C.103(a) as obvious over Saier et al (Journal of Biological Chemistry (1980), 255(18), 8579-84) or Chauvin et al. (Research in Microbiology, 1996, 147 (6-7), 471-9) and Powell et al. (J. Biol. Chem., 270 (9), 4822-4839, 1995) in view of US Patents 5698428 or 5700675.

The instant claim is drawn to a screening assay for the identification of antimicrobials that inhibit or uncouple enzyme I.

The importance of bacterial phosphotransferase system (PTS) is well recognized in the prior art. Powell et al. teach that the system mediates the uptake and concomitant phosphorylation of many carbohydrates and consists of several phosphoryl transfer proteins, such as soluble enzyme I and HPr, and membrane-bound enzyme I complex. In particular, enzyme I is recognized as essential first step of the PTS cascade which transfers phosphorylgroups from phosphoenolpyruvate. See, for

example Saier et al or Chauvin et al. Obviously, as Enzyme I is on the top of the PTS phosphorylation cascade, its inhibition should compromise cell growth. Thus PTS system is general, and enzyme I in particular, play a key regulatory role with respect to carbon metabolism in both Gram-negative and Gram-positive bacteria. See also admitted prior art, page 7. Therefore, it would be *prima facie* obvious to one skilled in the art that in view of the importance of enzyme I in bacterial metabolism, agents which impair the enzyme would be valuable antimicrobial agents. Accordingly, it would be obvious to search for antimicrobial agents among compounds capable to impair enzyme I and the phosphate transfer mediated by the enzyme.

Although the referenced prior art does not teach a particular screening assay for searching for agents which inhibit PTS system, various screening assays of inhibitors of phosphorylation reactions are well known in the art. See, e.g., US Patents 5698428, 5700675. One would be motivated to apply known assay methods to find new agents which inhibit phosphotransfer, because such agents will have an antimicrobial action which is a desired pharmacological effect.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to

5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 21, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb